DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 19, 2015

Spinal Elements, Incorporated
Julie Lamothe, Ph.D., M.B.A.
Regulatory Affairs and Quality Assurance Director
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K150061
Trade/Device Name: LUCENT®, LUCENT Ti-BOND®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 16, 2015
Received: March 18, 2015

Dear Dr. Lamothe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150061

Device Name
LUCENT®, LUCENT TI-BOND®

Indications for Use *(Describe)*
Lucent® and Lucent Ti-Bond® are intervertebral body fusion devices intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).
These devices are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).
These devices are intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with these devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
Lucent® and Lucent Ti-Bond®

510(k) Number: K150061

I. SUBMITTER

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Date Prepared: January 12th, 2015

II. DEVICE

Proprietary Name	Lucent®; Lucent Ti-Bond®
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Appliance, Fixation Spinal Intervertebral Body)
Proposed Regulatory Class	Class II
Device Product Code	MAX

III. PREDICATE DEVICE

Primary Predicate Name	Lucent®
Regulatory Class	Class II
Submission No	K071724
Device Code	MAX

Predicate Name	Lucent Ti-Bond®
Regulatory Class	Class II
Submission No	K110632
Device Code	MAX

Predicate Name	Lucent® Lateral
Regulatory Class	Class II
Submission No	K122967
Device Code	MAX

IV. DEVICE DESCRIPTION

The Lucent® device is an intervertebral body fusion device for use in lumbar spinal surgery. It may also be referred to as an interbody device or interbody cage. The device is generally box-shaped with various holes throughout its design to allow for the placement of autograft. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned.

V. INDICATION FOR USE

Lucent intervertebral body fusion devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

This device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is identical in indications for use, surgical technique, manufacturing method, raw material and instrumentation to the predicate devices cleared in K071724, K110632 and K122967. The difference to the Lucent device is the introduction of a rounded anterior end. The devices will be marketed with and without a plasma-sprayed porous titanium surface. The specifications and manufacturing of the titanium coating is identical to that of the predicate devices cleared in K110632 and K122967. In addition, line item configurations have been added to the Lucent line. These sizes do not constitute a smaller or larger footprint than the devices cleared in K110632 and K122967. Neither modification raises any new issues of safety or effectiveness.

VII. PERFORMANCE DATA

Biocompatibility Testing

Biocompatibility testing were performed in accordance with FDA Memorandum #G95-1 and ISO 10993-1 Part 1. The Lucent devices are considered permanent implant devices contacting tissue/bone. The PEEK material biocompatibility relevant to the device contact type is presented in Invibio device master file (MAF 1209). The titanium coating material is commercially pure titanium. The coating is in accordance with ASTMF 1580, which address the biocompatibility of the material. No further testing were required.

Electrical safety and electromagnetic compatibility (EMC)

No electrical and electromagnetic compatibility testing were performed.

Software Verification and Validation Testing

The device does not contain software. Therefore no software verification and validation testing were performed.

Mechanical testing

Non-clinical testing were used to support the decision of substantial equivalence. Non-clinical testing consisted of the following testing performed in accordance with the FDA guidance Class II Special Controls Guidance Document: Intervertebral Body Fusion Device:

- Static Compression
- Dynamic Compression

Animal Study

No animal studies were performed.

Clinical Studies

No clinical studies were performed.

VIII. CONCLUSIONS

Based on our analysis of the test data, the device performs comparably to the predicate device that is currently marketed for the same intended use.